ADVERSE EVENT	An unfavorable change in the health of a participant, including abnormal laboratory findings, that happens during a clinical study or within a certain time period after the study is over. This may or may not be caused by the intervention being studied. (See also **Adverse Events basic results data element on ClinicalTrials.gov.)**
ALLOCATION	A clinical trial design strategy used to assign participants to an arm of a study.
ARM	A group or subgroup of participants in a clinical trial who receives specific interventions, or no intervention, according to the study protocol. This is decided before the trial begins.
CONTROLLED TRIAL	A type of clinical trial in which observations made during the trial are compared to a standard (called the control). The control may be observations from a group of participants in the same trial or observations from outside the trial (for example, from an earlier trial, called a "historical control").
DOUBLE BLIND MASKING	A type of masking in which two or more parties involved with the clinical trial do not know which participants have been assigned which interventions. Typically, this includes the investigator and participant.
EXPANDED ACCESS	A process regulated by the Food and Drug Administration (FDA) that allows manufacturers to provide investigational new drugs to patients with serious diseases or conditions who cannot participate in a clinical trial.
EXPERIMENTAL ARM	A group of participants that receives the intervention that is the focus of the study.
MASKING (or Blinding)	A clinical trial design strategy in which one or more parties involved with the trial, such as the investigator or participant, do not know which participants have been assigned which interventions. Types of masking include none **Open label, Single blind masking, and Double blind masking.**
OPEN LABEL	Describes a clinical trial in which masking is not used. That means that all parties involved with the trial know which participants have been assigned which interventions.
RANDOMIZED ALLOCATION	A strategy in which participants are assigned to arms of a clinical trial by chance.
SHAM COMPARATOR ARM	A group of participants that receives a procedure or device that is made to be indistinguishable from the actual procedure or device being studied but does not contain active processes or components.
SINGLE BLIND MASKING	A type of masking in which one party involved with the clinical trial, either the investigator or participant, does not know which participants have been assigned which interventions.